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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,080	09/07/2006	Kenneth Gall	76775.011002	9897

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GREENBERG TRAURIG, LLP
1200 SEVENTEENTH STREET, SUITE 2400
DENVER, CO 80202

EXAMINER

MERENE, JAN CHRISTOP L

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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09/28/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,080	Applicant(s) GALL ET AL.	
	Examiner JAN CHRISTOPHER MERENE	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46,51,52,55,56 and 139-141 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46,51,52,55,56 and 139-141 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/29/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is based on the reply filed July 22, 2010 for 10/598,080 application filed on September 7, 2006 which is a 371 of PCT/US2006/012934 filed April 3, 2006, which claims priority to US Provisional Application 60/667,876, filed April 1, 2005.

Election/Restrictions

2. Applicant's election without traverse of Group II Species A in the reply filed on December 15, 2009 is acknowledged.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

Art Unit: 3733

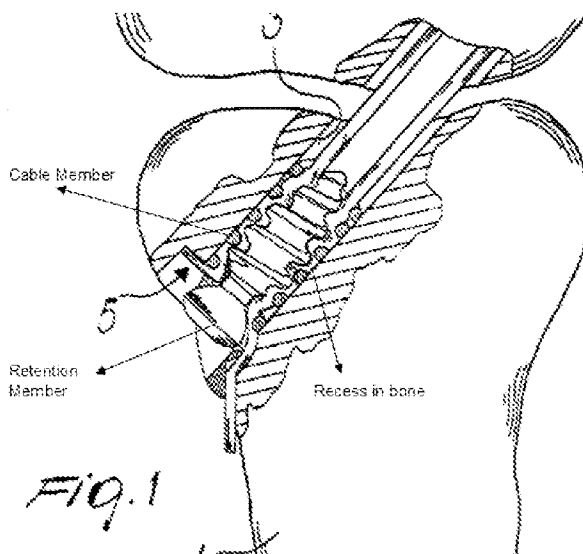
were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. **Claims 46, 51, 55, 139** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dovesi et al US 2002/0165547 in view of Lendlein et al (see IDS filed on 7/29/2010, NPL #66).

Regarding **Claim 46**, Dovesi discloses a method comprising:

inserting a cable member (#6) into a recess in a bone (see Fig below as well as Figs 2-4);

inserting a retention device (#7) into the recess, the retention device containing a shape memory material; and activating the shape memory material (as seen in Fig below and see paragraph 25-26, 30).



Regarding **Claim 51**, Dovesi discloses creating the cable member is selected from an animal tissue, a synthetic fiber, a natural fiber, a polymer, a metallic wire, a bundle, and a composite (as seen in Fig 2-4 and paragraph 30). Regarding **Claim 55**, Dovesi discloses the inserting the cable member operation precedes the inserting the retention device operation (see paragraph 25).

Dovesi discloses the use of a shape memory material but does not disclose the retention device containing a shape memory polymer such that is inserted in a temporary pre-implantation shape and causing the polymer to change shape after implantation.

However, Lendlein discloses that shape memory polymers allow for implants to be placed through small incisions (see introduction on page 1673), wherein shape memory polymers possess the ability to memorize permanent shape that can substantially differ from their initial temporary shape, wherein bulkier devices can be introduced into the body in a compressed temporary shape (see last paragraph at the end of page 1673 continuing to the top paragraph of page 1674), wherein the shape memory polymer can be activated by heating (see page 1674, 2nd and 3rd paragraphs starting with “The thermally induced shape memory effect ...”).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Dovesi to include a shape memory polymer in view of Lendlein because shape memory polymers are known shape memory

Art Unit: 3733

materials, wherein shape memory polymers allow for implants to be placed through small incisions, where shape memory polymers possess the ability to memorize permanent shape that can substantially differ from their initial temporary shape, wherein bulkier devices can be introduced into the body in a compressed temporary shape. The examiner notes that the heat from the body and when placed in the bone would cause the shape memory polymer to change shape.

7. **Claim 52** is rejected under 35 U.S.C. 103(a) as being unpatentable Dovesi et al US 2002/0165547 and Lendlein et al (see IDS filed on 7/29/2010, NPL #66), as applied to claim 46, 51 above, and in further view of Chan US 2002/0188298.

The combination of Dovesi and Lendlein disclose the claimed invention as discussed above, where the cable member can be natural or synthetic but does not disclose that it is made from human soft tissue.

However, Chan discloses a similar method with a cable member (L) and a retention device (#1 as seen in Fig 2), wherein the cable member is made from a human donor or the patient itself (see paragraph 8-9), wherein human tissue is a known material used for ligament construction/cable member construction (see paragraphs 6-9).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Dovesi and Lendlein to have the cable be made out of human soft tissue in view of Chan because human tissue is a known material used for ligament construction/cable member construction. It would have been

Art Unit: 3733

further obvious to one having ordinary skill in the art at the time the invention was made to have the cable member be made out of human soft tissue, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

8. **Claims 140-141** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dovesi et al US 2002/0165547 and Lendlein et al (see IDS filed on 7/29/2010, NPL #66), as applied to claim 46 above, and in further view of Boneau US 5,879,382.

The combination of Dovesi and Lendlein disclose the invention as discussed above but does not disclose, flooding the retention device with a liquid bath.

Boneau discloses a device made out of a shape memory material that is activated/ expanded by the use of heated fluids to cause expansion (see Col 2 lines 46-55).

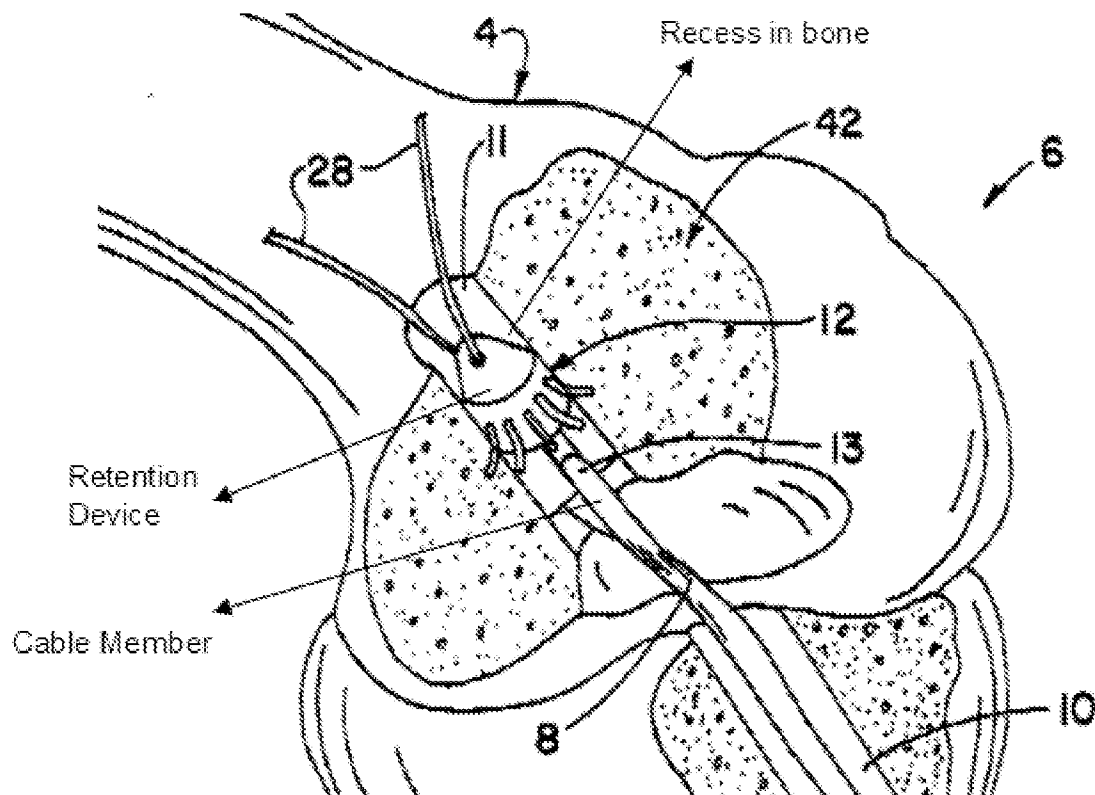
It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of combination of Dovesi and Lendlein to use a liquid bath in view of Boneau because it applies a known technique to a known device ready for improvement to yield predictable results of helping expand a shape memory material. The examiner notes that heat from the bath and body heat from the bone would activate the shape memory material.

9. **Claims 46, 56** are rejected under 35 U.S.C. 103(a) as being unpatentable over Li US 5,505,735 in view of Lendlein et al (see IDS filed on 7/29/2010, NPL #66) .

Regarding **Claim 46**, Li discloses a method comprising:

inserting a cable member (#8) into a recess in a bone (see Fig below);

inserting a retention device (#12) into the recess, the retention device containing a shape memory material; and activating the shape memory material (see Col 7 lines 20-30, where the retention device is made out of a shape memory material).



Regarding **Claim 56**, Li discloses inserting the cable member operation is performed simultaneously with the inserting of the retention device operation (see Fig above in claim 46, Fig 2, Col 8 lines 30-53, wherein the retention device has a hole for sutures #28 and a hole #30 for the cable member, where the sutures is pulled, wherein inserting the cable member and retention member is simultaneously performed).

Li discloses the use of a shape memory material but does not disclose the retention device containing a shape memory polymer such that is inserted in a

Art Unit: 3733

temporary pre-implantation shape and causing the polymer to change shape after implantation.

However, Lendlein discloses that shape memory polymers allow for implants to be placed through small incisions (see introduction on page 1673), wherein shape memory polymers possess the ability to memorize permanent shape that can substantially differ from their initial temporary shape, wherein bulkier devices can be introduced into the body in a compressed temporary shape (see last paragraph at the end of page 1673 continuing to the top paragraph of page 1674), wherein the shape memory polymer can be activated by heating (see page 1674, 2nd and 3rd paragraphs starting with “The thermally induced shape memory effect ...”).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Li to include a shape memory polymer in view of Lendlein because shape memory polymers are known shape memory materials, wherein a shape memory polymer is a simple substitution of one known shape memory material for another to obtain predictable results of expanding a shape memory material from a pre-implantation state to a post-implantation state, wherein shape memory polymers allow for implants to be placed through small incisions, where shape memory polymers possess the ability to memorize permanent shape that can substantially differ from their initial temporary shape, wherein bulkier devices can be introduced into the body in a compressed temporary shape.

Response to Arguments

10. Applicant's arguments with respect to claims above have been considered but are moot in view of the new ground(s) of rejection. The examiner notes that the applicant's amendment were directed to a shape memory polymer, where the applicant has provided numerous references showing the use of shape memory polymers in the art and their benefits for implanting devices made of such materials, see IDS filed 7/29/2010.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone

Art Unit: 3733

number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733